IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

CELGENE CORPORATION, **Plaintiff,** **v.** **SYNTHON PHARMACEUTICALS INC., SYNTHON B.V., SYNTHON S.R.O., and ALVOGEN PINE BROOK, LLC.** **Defendants.**	**COMPLAINT** **Civil Action No: 1:18cv0540**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against defendants Synthon Pharmaceuticals Inc. ("Synthon Pharmaceuticals"), Synthon B.V. ("Synthon B.V."), Synthon s.r.o. ("Synthon s.r.o.," together with Synthon Pharmaceuticals and Synthon B.V., "Synthon") and Alvogen Pine Brook, LLC. ("Alvogen") (collectively, "Defendants") alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from the filing of Abbreviated New Drug Application ("ANDA"), No. 210232, with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's POMALYST® drug products prior to the expiration of United States Patent Nos. 8,198,262 (the "'262 patent"), 8,673,939 (the "'939 patent"), 8,735,428 (the "'428

patent"), and 8,828,427 (the "'427 patent"), all owned by Celgene (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Synthon Pharmaceuticals is a North Carolina corporation, having a principal place of business at 1007 Slater Road, Suite 150 Durham, North Carolina 27703.

4. On information and belief, Synthon B.V. is a corporation organized and existing under the laws of the Netherlands, having a principal place of business at Microweg 22, P.O. Box 7071, 6503 CM Nijmegen, the Netherlands.

5. On information and belief, Synthon s.r.o. is a Czech Republic entity having a principal place of business at Brnenska 32/cp. 597, 678 01 Blansko, Czech Republic.

6. On information and belief, Alvogen is a Delaware corporation, having a principal place of business at 10B Bloomfield Avenue, Pine Brook, New Jersey 07058.

The Patents-in-Suit

7. On June 12, 2012, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '262 patent, entitled, "Methods for treating multiple myeloma using 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '262 patent is attached hereto as Exhibit A.

8. On March 18, 2014, the USPTO duly and lawfully issued the '939 patent, entitled, "Methods for treating multiple myeloma with 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '939 patent is attached hereto as Exhibit B.

9. On May 27, 2014, the USPTO duly and lawfully issued the '428 patent, entitled, "Methods for treating multiple myeloma with 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '428 patent is attached hereto as Exhibit C.

10. On September 9, 2014, the USPTO duly and lawfully issued the '427 patent, entitled, "Formulations of 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione," to Celgene as assignee of the inventors Anthony Tutino and Michael T. Kelly. A copy of the '427 patent is attached hereto as Exhibit D.

The POMALYST® Drug Product

11. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §

355(a), for pomalidomide capsules (NDA No. 204026), which it sells under the trade name POMALYST®. POMALYST® is an FDA-approved medication used for the treatment of multiple myeloma.

12. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide.

13. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to POMALYST®.

14. The labeling for POMALYST® instructs and encourages physicians, pharmacists, and other healthcare workers and patients to administer POMALYST® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

A. Synthon

17. This Court has personal jurisdiction over Synthon Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with the State of North Carolina. On information and belief, Synthon Pharmaceuticals Inc. is registered with

the State of North Carolina under SosId No. 1128782. On information and belief, Synthon Pharmaceuticals has purposefully conducted and continues to conduct business in this Judicial District, and has purposefully availed itself of the privilege of doing business in North Carolina.

18. On information and belief, Synthon Pharmaceuticals is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in ANDA No. 210232. On information and belief, Synthon Pharmaceuticals prepares and/or aids in the preparation and submission of ANDAs to the FDA.

19. On information and belief, Synthon B.V. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in ANDA No. 210232. On information and belief, Synthon B.V. prepares and/or aids in the preparation and submission of ANDAs to the FDA.

20. On information and belief, Synthon s.r.o is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States,

including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in ANDA No. 210232. On information and belief, Synthon s.r.o. prepares and/or aids in the preparation and submission of ANDAs to the FDA.

21. On information and belief, Synthon Pharmaceuticals maintains extensive and systematic contacts with pharmaceutical retailers, wholesalers, and/or distributors in North Carolina providing for the distribution of Synthon's products in the State of North Carolina, including in this Judicial District.

22. On information and belief, Synthon regularly and continuously transacts business within North Carolina, including by making pharmaceutical products for sale in North Carolina and selling pharmaceutical products in North Carolina, including in this Judicial District. On information and belief, Synthon derives substantial revenue from the sale of those products in North Carolina, including in this Judicial District.

23. This Court has personal jurisdiction over Synthon B.V. and/or Synthon s.r.o. because, *inter alia*, they: (1) have purposefully availed themselves of the privilege of doing business in North Carolina, including directly or indirectly through their subsidiary, agent, and/or alter ego, Synthon Pharmaceuticals, a company registered with the State of North Carolina; and (2) maintain extensive and systematic contacts with the State of North Carolina, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in North Carolina, including in this Judicial District, including through, directly or indirectly, Synthon Pharmaceuticals.

24. On information and belief, Synthon Pharmaceuticals acts at the direction, and for the benefit, of Synthon B.V. and/or Synthon s.r.o.

25. On information and belief, Synthon Pharmaceuticals, Synthon B.V., and Synthon s.r.o. are members of the same corporate family.

26. On information and belief, Synthon Pharmaceuticals, Synthon B.V., and Synthon s.r.o. work in concert with respect to the regulatory approval, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

27. On information and belief, Synthon Pharmaceuticals Inc., Synthon B.V., and/or Synthon s.r.o. have partnered with Alvogen in the submission of ANDA No. 210232 and will continue to partner with Alvogen towards the regulatory approval, manufacturing, use, importation, marketing, sale, offer for sale, and distribution of generic pharmaceutical products, including Synthon's Proposed Products, throughout the United States, including in North Carolina (including this Judicial District), prior to the expiration of the patents-in-suit.

28. This Court has personal jurisdiction over Synthon because, *inter alia,* it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Synthon submitted ANDA No. 210232 from this Judicial District. On information and belief, Synthon intends a future course of conduct that includes acts of patent infringement in North Carolina, including in this Judicial

District. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in North Carolina and in this Judicial District.

29. In the alternative, this Court has personal jurisdiction over Synthon B.V. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) Synthon B.V. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Synthon B.V. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Synthon B.V. satisfies due process.

30. In the alternative, this Court has personal jurisdiction over Synthon s.r.o. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) Synthon s.r.o. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Synthon s.r.o. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Synthon s.r.o. satisfies due process.

B. Alvogen

31. This Court has personal jurisdiction over Alvogen by virtue of, *inter alia*, its systematic and continuous contacts with the State of North Carolina. On information and belief, Alvogen is in the business of, among other things, manufacturing, marketing, offering for sale, selling, and importing pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Alvogen, as Alvogen, Inc., is registered to do business in the State of North Carolina under SosId No. 1289924. On information and belief, Alvogen has conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of drug products.

32. This Court has personal jurisdiction over Alvogen because, *inter alia*, it has purposefully availed itself of the privilege of doing business in North Carolina.

33. On information and belief, Alvogen derives substantial revenue from the sale of generic pharmaceutical products and/or active pharmaceutical ingredient(s) ("API") used in various generic pharmaceutical products sold throughout the United States, including in this Judicial District.

34. On information and belief, Defendants work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products and/or API throughout the United States, including in this Judicial District.

35. On information and belief, Alvogen partnered with Synthon and participated in the preparation and/or filing of ANDA No. 210232. On information and belief, Alvogen and will continue to partner with Synthon towards the regulatory approval, manufacturing, use, importation, marketing, sale, offer for sale, and distribution of generic pharmaceutical products, including Synthon's Proposed Products, throughout the United States, including in North Carolina, including in this Judicial District, prior to the expiration of the patents-in-suit.

36. On information and belief, Alvogen serves as a United States marketing partner with respect to ANDA No. 210232.

37. This Court has personal jurisdiction over Alvogen because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Alvogen intends a future course of conduct that includes acts of patent infringement in North Carolina, including in this Judicial District. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in North Carolina and in this Judicial District. This Judicial District is a likely destination for the generic drug product described in ANDA No. 210232. On information and belief, Alvogen intends to benefit from ANDA No. 210232 if ANDA No. 210232 is approved.

Acts Giving Rise To This Suit

38. Pursuant to Section 505 of the FFDCA, Defendants submitted ANDA No. 210232 seeking approval to engage in the commercial manufacture, use, offer for sale,

sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Synthon's Proposed Products"), before the patents-in-suit expire.

39. On information and belief, following FDA approval of ANDA No. 210232, Defendants Synthon and Alvogen will work in concert with one another to make, use, offer to sell, or sell Synthon's Proposed Products throughout the United States, or import such generic products into the United States.

40. On information and belief, in connection with the filing of ANDA No. 210232 as described above, Synthon provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Synthon's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in ANDA No. 210232.

41. No earlier than May 4, 2018, Synthon sent written notice of its Paragraph IV Certification to Celgene ("Synthon's Notice Letter"). Synthon's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in ANDA No. 210232. Synthon's Notice Letter also informed Celgene that Synthon seeks approval to market Synthon's Proposed Products before the patents-in-suit expire.

Count I: Infringement of the '262 Patent

42. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

43. Defendants' submission of ANDA No. 210232 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Synthon's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

44. There is a justiciable controversy between Celgene and Defendants as to the infringement of the '262 patent.

45. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Synthon's Proposed Products in the United States.

46. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Synthon's Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 210232, Defendants will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Synthon's Proposed Products in the United States. On information and belief,

Defendants have had and continue to have knowledge that Synthon's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Synthon's Proposed Products.

48. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '262 patent is not enjoined.

49. Celgene does not have an adequate remedy at law.

50. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '939 Patent

51. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

52. Defendants' submission of ANDA No. 210232 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Synthon's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

53. There is a justiciable controversy between Celgene and Defendants as to the infringement of the '939 patent.

54. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Synthon's Proposed Products in the United States.

55. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will induce infringement of one or more claims of the ’939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 210232, Defendants will intentionally encourage acts of direct infringement with knowledge of the ’939 patent and knowledge that its acts are encouraging infringement.

56. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will contributorily infringe one or more claims of the ’939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Synthon’s Proposed Products are especially adapted for a use that infringes one or more claims of the ’939 patent and that there is no substantial non-infringing use for Synthon’s Proposed Products.

57. Celgene will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’939 patent is not enjoined.

58. Celgene does not have an adequate remedy at law.

59. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count III: Infringement of the ’428 Patent

60. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

61. Defendants’ submission of ANDA No. 210232 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Synthon’s Proposed Products, prior to the expiration of the ’428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

62. There is a justiciable controversy between Celgene and Defendants as to the infringement of the ’428 patent.

63. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will infringe one or more claims of the ’428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States.

64. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will induce infringement of one or more claims of the ’428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 210232, Defendants will intentionally encourage acts of direct infringement with knowledge of the ’428 patent and knowledge that its acts are encouraging infringement.

65. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will contributorily infringe one or more claims of the ’428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Synthon’s Proposed Products are especially adapted for a use that infringes one or more claims of the ’428 patent and that there is no substantial non-infringing use for Synthon’s Proposed Products.

66. Celgene will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’428 patent is not enjoined.

67. Celgene does not have an adequate remedy at law.

68. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count IV: Infringement of the ’427 Patent

69. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

70. Defendants’ submission of ANDA No. 210232 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Synthon’s Proposed Products, prior to the expiration of the ’427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

71. There is a justiciable controversy between Celgene and Defendants as to the infringement of the ’427 patent.

72. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will infringe one or more claims of the ’427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States.

73. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will induce infringement of one or more claims of the ’427 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 210232, Defendants will intentionally encourage acts of direct infringement with knowledge of the ’427 patent and knowledge that its acts are encouraging infringement.

74. Unless enjoined by this Court, upon FDA approval of ANDA No. 210232, Defendants will contributorily infringe one or more claims of the ’427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Synthon’s Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Synthon’s Proposed Products are especially adapted for a use that infringes one or more claims of the ’427 patent and that there is no substantial non-infringing use for Synthon’s Proposed Products.

75. Celgene will be substantially and irreparably damaged and harmed if Defendants’ infringement of the ’427 patent is not enjoined.

76. Celgene does not have an adequate remedy at law.

77. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Defendants have infringed the patents-in-suit by submitting ANDA No. 210232;

(B) A Judgment that Defendants have infringed, and that Defendants' making, using, offering to sell, selling, or importing Synthon's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210232 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Synthon's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing

pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Synthon's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Defendants have committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Synthon's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: June 21, 2018

Respectfully submitted,

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